

Appln. No. 09/835,523  
Atty. Dkt. No. 054707-0661  
Response To Office Action Of October 7, 2004

### REMARKS

#### **I. Disposition Of The Claims**

Claims 1-40 and 48-51 are pending. Claims 5-6, 11-40 and 49-51 were withdrawn from consideration. Office action, page 2. Claims 1-4, 7-10 and 48 stand rejected.

The withdrawn claims should be rejoined. *See* MPEP §§ 803.02; 821.04.

Claims 1, 4 and 7 have been amended as shown. Support is in the specification as filed.

#### **II. Rejections Under 35 USC § 112, First Paragraph**

##### **A. Claims 1-4, 7-10 and 48**

Claims 1-4, 7-10 and 48 were rejected under 35 U.S.C. § 112, first paragraph, because the specification does not reasonably provide enablement for solvates of the compound of formula I. *See* Office action, page 3. The PTO acknowledged that the specification is enabling for a pharmaceutical salt. *See* Office action, page 3. Applicants traverse this rejection.

Claims are assumed enabled. MPEP § 2164.04. Indeed, when challenging a specification's enablement, the PTO must not only explain why it doubts a claim's presumptively enabling disclosure but also cite supporting evidence for its assertion. MPEP § 2164.04.

Claims 1-4, 7-10 and 48, nevertheless, were rejected without citing supporting evidence. Office action, page 3. Indeed, the thrust of the PTO's argument is that undue experimentation would have been required, since one of ordinary skill in the art would have had experiment in order to arrive at any one solvate. Simply, even if further experimentation were complex or required that fact would not necessarily mean such experimentation was undue. *See* MPEP § 2164.01.

Since claims are presumed enabled, and since the explanation and evidence of record provide no basis to infer that any claimed compound would not crystallize out as solvates, nothing of record casts doubt on the claims' enablement. Thus, the rejection should be reversed.

Appln. No. 09/835,523  
Atty. Dkt. No. 054707-0661  
Response To Office Action Of October 7, 2004

**B. Claims 7-10**

Claims 7-10 were rejected under 35 U.S.C. § 112, first paragraph, because the specification does not reasonably provide enablement for affecting a neuronal activity, preventing neurodegeneration, treatment of a neurological disorder, and preventing or treating Alzheimer's disease, Huntington's disease or ALS. Office action, page 3. The PTO set forth its reasoning on pages 3-6 of the Office action. Its findings, however, are unsupported by the evidence and explanation of record.

A specification which contains a statement of manner and process of using the invention must be taken as in compliance with the "how to use" requirement of 35 U.S.C. § 112, first paragraph, *unless* there is a reason to doubt the objective truth of the statement. *See In re Brana*, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995). In *Brana*, the court found the enablement requirement of 35 U.S.C. § 112, first paragraph, was met where, instead of a bare assertion of purported use, the specification describes the results of an *in vitro* screening assay. *See id.* As in *Brana*, the specification here presents more than a bare assertion of purported use. *See, e.g.,* Example 13, pages 101-105, of the specification.

The evidence or explanation of record contains nothing to doubt the teachings of the specification. For example, no evidence is cited to doubt the objective truth of the specification. *See* Office action, pages 3-6. Indeed, the PTO fails to even consider the working examples provided in the specification. *See* Office action, pages 3-6.

As such, this rejection is improper and should be withdrawn.

**III. Rejections Under 35 U.S.C. § 112, Second Paragraph**

Claims 1-4, 7-10 and 48 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. *See* Office action, page 2.

**A. "wherein said R1 group is either unsubstituted or additionally substituted"**

Claims 1-4, 7-10 and 48 were rejected under 35 U.S.C. § 112, second paragraph, for reciting "wherein said R1 group is either unsubstituted or additionally substituted." Office

Appln. No. 09/835,523  
Atty. Dkt. No. 054707-0661  
Response To Office Action Of October 7, 2004

action, page 2. The present claims avoid this issue. Accordingly, this rejection should be withdrawn.

**B. "carbocycle", "heteroaryl", and "heterocycle"; "ester or solvate thereof"; "thiocarbonyl" and "carbonyl"; or "affecting a neuronal activity"**

Claims 1-4, 7-10 and 48 were rejected under 35 U.S.C. § 112, second paragraph, for reciting "carbocycle", "heteroaryl", and "heterocycle"; "ester or solvate thereof"; "thiocarbonyl" and "carbonyl"; or "affecting a neuronal activity". Office action, pages 2-3. Applicants traverse these rejections.

The claims as written are definite, as the plain meaning of these terms would be readily understood by a person of ordinary skill in the art. The scope is perhaps broad.

However, a broad claim is not indefinite for the purposes of 35 U.S.C. § 112, second paragraph, as long as the boundaries of the claim are capable of being understood. *See In re Gardner*, 427 F.2d 786, 788, 166 USPQ 138, 140 (CCPA 1970); *see also* MPEP § 2173.04. As long as the scope of the claim, when read in light of the specification, is clear to one of ordinary skill in the art, the definiteness requirement has been met. *See, e.g., Slimfold Mfg. Co. v. Kinkead Indus.*, 810 F.2d 1113, 1116-17, 1 USPQ2d 1563, 1566-67 (Fed. Cir. 1987). Consequently, a broad claim that employs well-known language conventionally used in the art should not be objectionable under 35 U.S.C. § 112, second paragraph. *See, e.g., In re Miller*, 441 F.2d 689, 692-93, 169 USPQ 597, 599 (CCPA 1971); *In re Kamal*, 398 F.2d 867, 870, 158 USPQ 320, 322 (CCPA 1968). Such is the case for each term recited here.

Accordingly, the claims are definite, and withdrawal of this ground for rejection is respectfully requested.

**IV. Non-Statutory Double Patenting Rejections**

Claims 1-4, 7-10 and 48 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No.

Appln. No. 09/835,523  
Atty. Dkt. No. 054707-0661  
Response To Office Action Of October 7, 2004

6,417,189 (US '189). Office action, page 7. The PTO stated its position on page 7 of the Office action.

Applicants respectfully request that the PTO hold this rejection in abeyance until such a time as allowable subject matter is indicated.

V. Conclusion

It is submitted that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned attorney by telephone, or Robert M. Norway at (202) 295-4024, if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

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The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 CFR § 1.136 and authorize payment of any such extensions fees to Deposit Account No. 19-0741.